

APPLICATION

of

Fred H. Burbank

Michael L. Jones

Greig Altieri

R. J. Serra

Ed Olson

and

Yu-Tung Wong

for

UNITED STATES LETTERS PATENT

on

**TENACULUM-LIKE DEVICE FOR INTRAVAGINAL INSTRUMENT DELIVERY**

Sheets of Drawings: Nine (9)

Atty. Docket No.: R0368-04000

## **TENACULUM-LIKE DEVICE FOR INTRAVAGINAL INSTRUMENT DELIVERY**

### **RELATED APPLICATIONS**

This application is a continuation-in-part of copending application Serial No. 10/300,420, filed on November 19, 2002, which is relied upon for priority and which is incorporated herein in its entirety.

### **FIELD OF THE INVENTION**

**[0001]**The invention generally relates to the field of holding and manipulating body tissue such as a female patient's uterine cervix in the treatment of various uterine disorders.

### **BACKGROUND OF THE INVENTION**

**[0002]**It is often desirable to hold, maneuver, and retain tissue during medical procedures. Devices for gripping, holding, and manipulating tissue are thus often very useful during medical procedures, particularly ones involving tissues, organs, and structures that are relatively inaccessible or otherwise difficult to reach or to retain.

**[0003]**In many medical procedures, it is useful to locate the cervix and cervical os of a female patient. For example, location of the cervical os and cervix is necessary for proper positioning for the performance of a dilatation and curettage procedure. In order to perform a hysterectomy, particularly with a transvaginal approach, it is often useful to grasp the cervix. This may aid in orienting the uterus, in reducing unwanted motion of the uterus during a procedure, or to

manipulate the uterus into a favorable position during treatment. Devices and methods for grasping, retaining and manipulating a uterus may be useful in many other medical procedures as well.

[0004]A hysterectomy (surgical removal of the uterus) is performed on approximately 800,000 women annually in the United States and is often the therapeutic choice for the treatment of uterine cancer, adenomyosis, menorrhagia, uterine prolapse, dysfunctional uterine bleeding (abnormal menstrual bleeding that has no discrete anatomic explanation such as a tumor or growth), and muscular tumors of the uterus, known as leiomyoma or uterine fibroids.

[0005]However, hysterectomy is a drastic treatment, entailing the removal of the uterus and the resulting loss of reproductive function. Thus, any method which can approximate the therapeutic result of a hysterectomy without removing the uterus would be a significant improvement in this field. Newer treatment methods have been developed for some diseases which may spare these women a hysterectomy.

[0006]In 1995, it was demonstrated that uterine fibroids could be treated without hysterectomy using a non-surgical therapy, specifically comprising bilateral intraluminal occlusion of the uterine arteries (Ravina et al., "Arterial Embolization to Treat Uterine Myomata", Lancet Sept. 9, 1995; Vol. 344; pp. 671-692, incorporated in its entirety herein). This technique is known as "uterine artery embolization". In this technique, uterine arteries are accessed via a transvascular route from a common femoral artery into the left and right uterine

arteries and embolic coils are deposited in the uterine arteries to occlude the arterial passageways

[0007]The uterus has a dual (or redundant) blood supply, the primary blood supply being from the bilateral uterine arteries, and the secondary blood supply from the bilateral ovarian arteries. Consequently, when both uterine arteries are occluded, i.e. bilateral vessel occlusion, the uterus and the fibroids contained within the uterus are both deprived of their blood supply. However, as demonstrated by Ravina et al., the effect on the fibroid is greater than the effect on the uterus. In most instances, the fibroid withers and ceases to cause clinical symptoms. See also Burbank, et al., "Uterine Artery Occlusion by Embolization or Surgery for the Treatment of Fibroids: A Unifying Hypothesis- Transient Uterine Ischemia," The Journal of the American Association of Gynecologic Laparoscopists, November 2000, Vol. 7, No. 4 Supplement, pp. S3-S49. U.S. Patent No. 6,254,801, to Burbank et al., entitled "Methods for Occlusion of the Uterine Arteries," describes numerous devices and methods useful for occluding a uterine artery by penetrating the tissue of the patient to access the uterine artery, which is incorporated herein in its entirety by reference.

[0008]However, catheter-based uterine artery embolization under radiologic direction requires specialized equipment and sophisticated procedures. Accordingly, far fewer uterine artery embolizations than hysterectomies are performed for uterine fibroids which are symptomatic.

[0009]What is needed, therefore, are devices and methods to locate, retain and manipulate the cervix, uterus and related tissues and near-by anatomical

structures that can be used by physicians in a simple clinical setting or environment to aid in therapeutic procedures.

### **SUMMARY OF THE INVENTION**

**[0010]** The invention is directed to tenaculum-type devices for intravaginally guiding therapeutic or diagnostic instruments to a female patient's uterine cervix and related tissue or nearby anatomical structures of the female patient and the methods of using such devices in the treatment of uterine disorders and other maladies.

**[0011]** Devices embodying features of the invention have an elongated guide rail with a distal guide rail portion configured for non-traumatic entry and advancement through the patient's vaginal canal into the patient's cervical os. In addition to the guide rail, the device has a tissue grasping mechanism secured to a distal portion of the guide rail proximal to the distal tip for gripping the patient's uterine cervix and related tissue or near-by anatomical structures.

**[0012]** The tissue grasping mechanism is secured to the guide rail so as to not interfere with the advancement of a therapeutic or diagnostic instrument over the guide rail to the patient's uterine cervix. The tissue grasping mechanism preferably has a first elongated member or handle with a proximal section configured for manual manipulation outside of the patient and a distal section with a distal end secured to a distal portion of the guide rail proximal to the atraumatic distal tip. The tissue grasping mechanism also has a second elongated member or handle with a proximal section configured for manual manipulation outside the patient in conjunction with the proximal section of the

first elongated member and a distal section with a tissue grasping distal end. The second elongated member is pivotally connected to the first elongated member at a pivot point proximally spaced from the distal end of the first elongated member so that the tissue grasping distal end of the second elongated member grasps uterine cervical tissue or related tissue or near-by anatomical structure against the guide rail.

[0013] The cervical canal of women who have not given birth is usually sufficiently small that the distal tip of the guide rail fits snugly within the canal. However, with women who have given birth, their cervical canal can be too large to provide a tight fit to the distal end of the guide rail. In those instances, it is recommended that the distal end of the guide rail be configured to expand once inside the patient's cervical canal to provide a better fit within the canal.

[0014] A tenaculum-like device having features of the invention may be used to guide, stabilize, anchor, or otherwise control the positional relationship between the patient's uterine cervix and another instrument, such as a uterine artery occlusion device. The tenaculum-like device may be provided with a locking feature, such as conventional ratchet type connectors at the proximal ends of the handles which are effective to maintain the axial position of the guide rail relative to the axis of the cervix while a therapeutic or diagnostic device, such as a uterine artery occlusion device, is mounted on and advanced over the guide rail.

[0015] The guide rail on the tenaculum-type device may be provided with an instrument driving mechanism, preferably an instrument driving mechanism which can be operated outside of the patient, when the tenaculum-type device is

deployed within the patient's vaginal canal. In one present embodiment, the portion of the guide rail which is proximal to the portion disposed within the patient's cervical canal is at least partially threaded and a driving member with a threaded passageway is mounted on the tressed portion of the guide rail. One or more elongated arms are secured to the threaded driving member and have free ends which extend out of the patient. The physician or other attendant may manipulate the elongated arms to rotate the threaded driving member about the threaded portion of the guide rail. The instrument to perform the procedure is slidably mounted on the guide rail and the threaded drive member on the threaded portion of the guide rail engages the instrument and drives the instrument along the rail to the female patient's uterine cervix, related tissue or near-by anatomical structure.

**[0016]**The one or more handles or proximal extremity of the tenaculum-like device embodying features of the invention may be at least in part detachable so that once an instrument has been put into operative position within the patient's vaginal canal, the one or more handles or proximal portion of the tenaculum-like device which extend out of the patient may be detached from the tenaculum-like device. This allows the distal portion of the tenaculum-like device to be sufficiently contained within the patient's vaginal canal to provide greater mobility and comfort to a patient during treatment.

**[0017]**When using the tenaculum-type device embodying features of the invention, the device is advanced through the patient's vaginal canal, the non-traumatic sound or distal tip of the device is inserted into the patient's cervical os

and advanced into the cervical canal. The handles which extend out of the patient are closed together to cause the tissue grasping member on the distal end of one of the handles to grasp the patient's uterine cervix or surrounding anatomical structure to fix the position of the cervix with respect to the guide rail. The medical instrument, such as a uterine artery occlusion clamp or other pressure applying occluding device, is mounted on the guide rail and advanced over the rail until properly positioned adjacent to the patient's vaginal fornix. When the patient's uterine arteries are located (e.g. by Doppler ultrasound blood flow sensors) the pressure applying surfaces of the clamps or other devices are urged against the wall of the patient's vaginal fornix with sufficient pressure to occlude the uterine arteries.

**[0018]**The devices and methods embodying features of the invention thus provide tools and methods to aid in the treatment of uterine diseases and conditions, including uterine fibroids, adenomyosis, dysfunctional uterine bleeding (DUB), post-partum hemorrhage, and other uterine disorders. The devices and methods are simple and easy to use and provide many advantages over other presently available methods and devices for such treatments.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0019]**Figure 1 is a perspective view of a tenaculum-like device embodying features of the invention.

**[0020]**Figure 1A is a transverse cross-sectional view of the device shown in Figure 1 taken along the lines 1A-1A.

[0021]Figure 1B is a transverse cross-sectional view of the device shown in Figure 1 taken along the lines 1B-1B.

[0022]Figure 2 is a perspective view of a tenaculum-like device similar to that shown in Figure 1 with removable handles.

[0023]Figure 3 illustrates a tenaculum-like device as shown in Figure 1 with a uterine artery occlusion clamp mounted on the guide rail of the tenaculum-like device.

[0024]Figure 4 is a perspective view of another embodiment of a tenaculum like device embodying features of the invention with the tissue grasping element in a disengaged configuration.

[0025]Figure 5 is a longitudinal cross-sectional view of the tenaculum-like device illustrated in Figure 4 taken along line 5-5.

[0026]Figure 6 is a perspective view of the tenaculum-like device shown in Figure 4 with the tissue grasping element in a tissue engaged configuration.

[0027]Figure 6A is a transverse cross-sectional view of the tenaculum-like device illustrated in Figure 6 taken along line 6A-6A.

[0028]Figure 7 is a perspective view of a tenaculum-like device as shown in Figure 4 after separation of a distal portion from a proximal portion.

[0029]Figure 8 illustrates a tenaculum-like device as shown in Figure 4 with a uterine artery occlusion clamp mounted on the guide rail of the tenaculum-like device.

[0030] Figure 9 is a schematic diagram of a reproductive system of a human female illustrating the placement of a tenaculum-like device embodying features of the invention partially disposed within the cervical os of a female human patient.

#### **DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION**

[0031] Figure 1 illustrates a tenaculum-type device 10 embodying features of the invention which has an elongated guide rail 11 and an attached tissue grasping mechanism 12. The elongated guide rail 11 has a distal portion 13 with a distal tip or sound 14 and a proximal portion 15 with a free proximal end 16 and is configured to guide a medical instrument (such as an occlusion device shown in Figure 3) toward the distal portion of the guide rail. The tissue grasping mechanism 12 is secured to the distal portion 13 of the guide rail 11 by connecting plate 17 proximal to the distal tip 14 and is configured to grasp and stabilize the patient's uterine cervix, related tissue or near-by anatomical structure to facilitate delivery of a medical instrument over the guide rail to the patient's uterine cervix.

[0032] The tissue grasping mechanism 12 has a first elongated member or handle 18 which has a proximal section 19 configured for manual manipulation and a distal section 20 with a distal end 21 secured to connecting plate 17. The tissue grasping mechanism 12 also has a second elongated member or handle 22 which has a proximal section 23 configured for manual manipulation and a distal section 24 with a tissue grasping distal end or spike 25. The first and

second elongated members 18 and 22 are pivotally connected at a pivot 26 proximally spaced from the distal ends of the first and second elongated members 18 and 22. Rotation of the second elongated member 22 about the pivot 26 adjusts the position of the tissue grasping distal end 25 with respect to the guide rail 11 to enable the tissue grasping distal end 25 to grasp uterine cervical tissue against the guide rail 11. In some instances the tissue grasping distal end 25 may penetrate through the cervical wall of the patient. The proximal ends of the first and second elongated members 17 and 22, which are configured to extend out of the patient during the procedure, are provided with finger grips 27 and 28 respectively to facilitate manual manipulation. The proximal ends are also provided with ratcheted locking members 30 and 31 respectively to releasably secure the proximal ends of the elongated members 18 and 22 together.

[0033]The guide rail 11 has a threaded outer portion 32 on at least a portion of its length and a distal collar 33 having internal lumen which allows slidable motion over the threaded outer portion 32 of the guide rail. A driving member 34 forms the proximal portion of the guide rail 11 and has an inner lumen 35 extending therein as shown in Figure 1A. The connecting member 36 forms the distal end of the driving member 34 and has internal threads which mate with the threads on the threaded outer portion 32 of the guide rail 11. Adjusting knob 37 forms the proximal portion of the driving member 34. Rotation of the knob 37 on the driving member 34 adjusts the position of the distal collar 33 on the threaded outer portion 32 and thereby may drive a treatment or diagnostic device, such as

the occlusion device shown in Figure 2, to the patient's uterine cervix which is slidably mounted on the threaded outer portion 32.

[0034] Tenaculum-like devices 10 are configured to engage other therapeutic or diagnostic instruments such as uterine artery occlusion devices which treat uterine disorders by applying pressure to the patient's uterine artery to restrict or terminate blood flow through the artery. One example of such an instrument is uterine artery occlusion device 40 shown in Figure 2 mounted on tenaculum like device 10. The uterine artery occlusion device 40 has pressure-applying clamping elements 41 and 42 configured to fit on both sides of the patient's uterine cervix and press against the patient's vaginal fornix in order to occlude the patient's uterine arteries. Details of uterine artery occlusion devices with pressure-applying elements are disclosed in co-pending U.S. patent application Serial No. 10/300,116 filed on November 19, 2002, entitled "Occlusion Device with Deployable Paddles for Detection and Occlusion of Blood Vessels" and application Serial No. 10,300,495 entitled "Deployable Constrictor for Uterine Artery Occlusion," by Fred H. Burbank et al., assigned to the present assignee. Both applications are hereby incorporated by reference in their entirety.

[0035] As shown in Figure 3, uterine artery occlusion device 40 is operatively connected to the guide rail 11 of tenaculum-like device 10 by an attachment sleeve 43, which is configured to at least partially surround or enclose a portion of guide rail 11 so as to be longitudinally movable on the guide rail. Distal sliding movement of attachment sleeve 43 moves uterine artery occlusion device 40 along the path defined by guide rail 11. Movement of the occlusion device 40

along the guide rail 11 may be effected manually, mechanically (such as the drive member 33) or by other suitable means. However, as described above, preferably the driving member 33 engages the attachment sleeve 43 (to which the occlusion device 40 is secured) so that rotation of the adjustable knob 36 causes movement of the occlusion device 40 along the guide rail 11.

**[0036]**As shown in Figure 3, the proximal portions 19 and 23 of the tissue grasping mechanism 12 of the tenaculum-like device 10 may be configured to be removable during use. This allows the distal portion of the tissue grasping mechanism 12 and the guide rail to remain in the patient's vaginal canal during the time period in which the patient's uterine arteries are being occluding by the occluding device 40 mounted on the guide rail 11. Removal of the proximal portions 19 and 23 provides greater comfort and freedom of movement to a patient receiving treatment. The removable proximal portions 19 and 23 may be connected by suitable means such as a threaded connection or with a bayonet-detent connection to the remaining portions of the tissue grasping members.

**[0037]**The tenaculum-like device 10 is inserted into the patient's vaginal canal and advanced therein until the distal tip 14 or sound of the guide rail 11 enters the patient's cervical os. The distal tip 14 of the guide rail 11 is advanced well into the patient's cervical canal for suitable placement that will guide a therapeutic or diagnostic device into a desired location. The tenaculum-like device 10 may be secured in place by pressing the proximal portions 19 and 23 of the first and second elongated members so that the tissue grasping element or spike 25 is pressed into cervical tissue. One or more spikes 25 may be disposed

on the distal end of the first elongated member 18 to press into cervical tissue in order to retain the tenaculum-like device 10 in place. It will be understood that other retention elements configured to retain a tenaculum-like device 10 in place within or on a patient's body, such as serrations, grooves, or other elements, may be employed.

[0038]Once the tenaculum-like device 10 is secured, an operator may then manipulate the patient's uterine cervix to place the tissue in a desired position or orientation for a subsequent procedure such as uterine artery occlusion. For example, by pulling on the handles 18 and 23 of the tenaculum-like device 10, the tissue next to the cervix, such as the vaginal fornix is stretched, which in turn pulls the uterine arteries towards the vagina so that these arteries are more readily compressed for occlusion. A therapeutic or diagnostic device, such as occlusion device 40, may be attached to the guide rail 11 of tenaculum-like device 10 either before placement of the tenaculum-like device within a patient's vagina or it may be attached at a later time, such as after a tenaculum-like device 10 has been secured to the patient's cervical tissue.

[0039]An alternative tenaculum-like device 50 embodying features of the invention is depicted in Figures 4-8. The tenaculum-like device 50 has an elongated shaft 51 with a tissue grasping mechanism 52 on the distal portion of the shaft. The tissue grasping mechanism 52 has an elongated arm 53 with a tissue engaging member or spike 54 at the distal end of the arm 53. Outer sheath member 55 is slidably disposed about a portion of the shaft 51 and is provided with handle member 56 for advancing the sheath member over the

shaft in order for the distal end 57 of the sheath to slide over the outwardly extending arm 53 to drive the arm toward the shaft 51 and the tissue engaging member or spike 54 into the patient's uterine cervix 58 (which is shown in phantom in Figures 6 and 7). The outer sheath 55 has a longitudinally oriented slot 60 which is configured to receive the pin 61 on the distal portion 62 of the shaft 51. The longitudinally oriented slot 60 extends to the circumferentially oriented slot 63 which allows the outer sheath 55 to be locked onto the shaft 51 with the tissue grasping element or spike 54 engaging the patient's uterine cervix 58 as shown in Figure 6. A wide variety of other locking means may be employed to lock the spike 54 in position. The distal portion 62 of the shaft 51 has a sound 64 with a rounded, non-traumatic distal tip 65.

[0040]As shown in Figure 4-6 the outer sheath 55 is separated into proximal portion 66 and distal portion 67. The distal end of the proximal portion 66 has a semi-circular step 68 which engages the semi-circular step 70 on the proximal end 71 of the distal portion 67. Distal thrusting and rotation of the proximal portion 66 causes the semi-circular steps 68 and 70 to engage, drive and rotate the proximal portion 67 so as to place the locating pin 61 on the distal portion of the shaft 51 within the longitudinally oriented slot 60 and ultimately into the locking circumferentially oriented slot 63. As shown more clearly in Figure 6A, the upper surface of the distal portion 62 of the shaft 51 has a D-shaped recess 72 configured to receive the proximal end 73 of arm 53 to provide a smoother outer surface so that when the distal end 57 of the outer sheath 55 slides distally it slides over the arm so that the spike 54 on the distal end of the arm engages

the patient's uterine cervix. The proximal end 73 of arm 53 disposed within the D-shaped recess 72 may be welded, pinned, glued, or otherwise fixedly attached to shaft 14 within the recess. The arm 53 may be made with metal, such as stainless steel, or other durable, flexible material, including polymers. As shown the arm 53 is formed so as to extend radially away from the distal portion 62 of the shaft 51. Alternatively, the joint between the proximal end 73 of arm 53 may include a spring, or a hinged joint, or both so as to bias the distal end of the arm having the tissue grasping element or spike 54 away from the shaft 51 to facilitate receiving the patient's uterine cervix.

[0041]As best shown in Figures 5 and 7, the elongated shaft 51 may be formed of proximal and distal shaft sections 74 and 75 respectively which are held together by elongated threaded member 76 which extends through the inner lumen 77 of proximal shaft section 74 and which has a threaded distal end 78 which is threadably connected to the threaded proximal end 80 of distal shaft section 75. The distal end of the proximal shaft section 74 is provided with an inner shoulder 81 which receives the proximal end 80 of the distal shaft section 74. Clockwise rotation of the enlarged knurled end 82 of the threaded member 76 tightens the connection between the proximal and distal shaft sections 74 and 75.

[0042]Once the tenaculum-like device 50 and any device delivered by the tenaculum like device has been intravaginally deployed with the tissue grasping mechanism 52 locked in place, the proximal shaft section 74 and the proximal portion 66 of the outer sheath 55 may be detached by rotating the enlarged

knurled end 82 in a counter clockwise direction to unscrew the threaded member 76 from the proximal end of the distal shaft section 75, leaving the distal shaft section and the distal portion 67 of the outer sheath 55 so that any device mounted on the tenaculum-like device 10 remains engaged with a cervix 58. This disengagement eliminates the proximal portion of the tenaculum-like device 10 from extending out of a patient's vagina and the accompanying discomfort and inconvenience during a procedure. At the end of the procedure the proximal portion 66 of the outer sheath 55 may be re-engaged with the proximal end of the distal portion 56 of the sheath 55 to unlock the tissue grasping mechanism 12 so that the remainder of the tenaculum-like device 10 and any treatment or diagnostic device still attached to be removed from the patient.

**[0043]** Figure 8 illustrates a uterine artery occlusion device 85, described in detail in copending application Serial No. 10/300,116, secured to the distal portion of the tenaculum-like device 50. The paddle-like members 86 and 87 are configured to engage both sides of the patient's uterine cervix to occlude both uterine arteries. The occlusion device 85 may be advanced over the tenaculum-like device 50 manually or in a manner similar to that shown in the previously discussed embodiment shown in Figures 1-3.

**[0044]** A schematic diagram of female human reproductive anatomy and related structures is shown in Figure 9, illustrating the placement and use therein of tenaculum-like device 50 previously described. The anatomical features shown in Figure 9 include uterus 90, vaginal canal 91, uterine cervix 92, vaginal fornix 93, cervical os 94, and uterine arteries 95 and 96 (which provide a large fraction

of the uterine blood supply). A uterine fibroid 97 within the uterine wall is also illustrated. As discussed above, and as disclosed in U.S. application serial number 09/908,815, filed July 20, 2001, to Burbank et al. ("815 application"), co-assigned with the present application, the entire contents of which are incorporated by reference herein, reduction or termination of blood flow in the uterine arteries is effective to treat uterine fibroids and other disorders of a female patient's uterus. The uterus 90 is accessed via vaginal canal 91 and through uterine cervix 92. The vaginal canal 91 has a wall forming the vaginal fornix 93 adjacent uterine cervix 92. The sound 64 extends through the cervical os 94 into the cervical canal 97. Arm 53 is pressed toward the sound 64 so that the spike 54 engages the exterior of uterine cervix 92. With the uterine cervix firmly secured, the tenaculum-type device may be employed to adjust the position of the cervix to facilitate the advancement of medical instruments over the shaft of the tenaculum-like device 50 to the uterus. The uterus 90 is supplied with blood predominantly by the uterine arteries 95 and 96 with lesser amounts coming from the patient's ovarian arteries. By advancing the uterine artery occlusion device such as that shown in Figure 8 (or Figure 2), to press the paddles thereof against the patient's vaginal fornix, the underlying uterine arteries may be occluded when the paddles are close and locked in position.

**[0045]** The uterine cervical canal of a woman who has not given birth is usually tight enough to firmly hold the sound of the tenaculum-type device embodying features of this invention within the canal with the tissue grasping mechanism engaged with the patient's uterine cervix. However, the uterine

cervical canal of a woman who has given birth is frequently too dilated to effectively retain the sound within the patient's uterus even with the tissue grasping mechanism engaged with the cervical tissue. For these situations, as shown in Figure 10, the sound 100 may be expanded to provide a more snug fit within the patient's cervical canal. The curvatures  $R_1$  and  $R_2$  of the expanded bifurcated portions 101 and 102 of the sound 100 may be varied to provide the desired expansion for effective retention of the sound portions 101 and 102. The bifurcated sound portions 101 and 102 may be held together mechanically or otherwise in an unexpanded condition to facilitate insertion into the patient cervical os. However, once the bifurcated sections 101 and 102 are disposed well within the patient's cervical canal, the restraint used to hold the bifurcated sections together can be removed to allow the expansion of the bifurcated structure. A circular collar 103 may be moved distally along the shaft of the tenaculum type device to close the expanding sound portions 101 and 102. Once the sound 100 is in position within the patient's cervical canal, the restraint collar 103 may be proximally withdrawn from the sound 100 to allow the expansion of the sound portions 101 and 102. The expandable sound 100 may be used in either the embodiment shown in Figures 1-3 and the embodiment shown in Figures 4-8, previously described.

**[0046]**While particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited to the specific embodiments illustrated, but is to be defined by

the scope of the appended claims as broadly as the prior art will permit, and in view of the specification if need be. Moreover, those skilled in the art will recognize that features shown in one embodiment may be utilized in other embodiments. Terms such as "element", "member", "device", "section", "portion", "step", "means" and words of similar import when used in the following claims shall not be construed as invoking the provisions of 35 U.S.C. §112(6) unless the claims expressly use the terms "means" or "step" followed by a particular function without setting forth specific structure (in the case of "means") or action (in the case of "step"). All patents and patent applications referred to above are hereby incorporated by reference in their entirety.